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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO.
09/990,613	11/21/2001	Reen Wu	UC072.001A	3887

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EXAMINER
LI, QIAN J

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 05/06/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	09/990,613	WU ET AL.
	Examiner	Art Unit
	Q. Janice Li	1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *6-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11/21/01 & 2/7/02* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-5, in Paper No. 12 is acknowledged. The traversal is on the ground(s) that claims 6-12 concern host cells comprising the nucleic acid specified in claims 1-5 do not refer to transgenic animals. Applicants requested to examine at least claims 6-12 along with the Group I claims. In response, claims 6-12 are grouped with the transgenic animals because the host cell of claims 6-12 embraces a host cell from a transgenic animal comprising the nucleic acids of claims 1-5. The host cells of claims 6-12 and claim 13 are structurally indistinguishable, whether the cells are present in or isolated from a non-human transgenic animal, they are structurally the same and thus are not patentably distinct. Therefore, claims 6-12 as written could not be placed in a different inventive group of claim 13. In order to examine claim 6-12, the group drawn to a transgenic animal has to be examined, which would place a severe burden on the Office if the two groups are examined together in this application. Therefore, it is maintained that the inventions are distinct products that belong to different biological entities due to their divergent subject matter, and they require different search criteria and technical considerations. The search for groups II and I would have certain overlap, but they are not co-extensive. Further search of these inventions is not co-extensive, as indicated by the separate classifications. The requirement is still deemed proper and is therefore made **FINAL**.

Please note that after a final requirement for restriction, the Applicants, in addition to making any response due on the remainder of the action, may petition the Commissioner to review the requirement. Petition may be deferred until after final action on or allowance of claims to the invention elected, but must be filed not later than appeal. A petition will not be considered if reconsideration of the requirement was not requested. (See § 1.181.).

Claims 1-32 are pending, however, claims 6-32 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claims 1-5 are under current examination.

Please note in light of the search report for SEQ ID No: 31, SEQ ID No: 32 has been searched and will be examined together with SEQ ID No: 31 in this Office action.

Specification

The specification contains sequence disclosures (figures 6A-H, 8, 10, 11A-B, and 12) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2) but are not identified by sequence identifier numbers in the Brief Description of the Drawings. Applicant must provide sequence identifiers in the specified section, and in the case that these sequences are not included in the original sequence submission, a paper copy and a computer readable copy of the Sequence Listing and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new

matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). A full response to this Office Action must include a complete response to the requirement for a Sequence Listing.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The methodology for determining adequacy of Written Description to convey that applicant was in possession of the claimed invention includes determining whether the application describes an actual reduction to practice, determining whether the invention is complete as evidenced by drawings or determining whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention (*Guidelines for Examination of Patent Applications under 35 U.S.C. § 112, p 1 "Written Description" Requirement;* Federal Register/ Vol 66. No. 4, Friday, January 5, 2001; II Methodology for Determining Adequacy of Written Description (3.)).

Claim 1 is drawn to an isolated nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of SEQ ID Nos: 31 and 32. The specification teaches that SEQ ID Nos: 31 and 32 are fragments of genomic sequence of mucin 5B gene that have promoter activities (Specification, paragraph 0011, 0025, figs. 13-16). Given the broadest reasonable interpretation, claim 1 embraces any heterologous nucleic acids that contain a mucin 5B promoter, and a genus of nucleic acid molecules that are either the full length or various fragments or allelic variants of genomic sequences of mucin 5B gene. The specification teaches that the MUC5B genomic structure is partially known, that the exons and introns of MUC5B encompass approximately 39076 base pairs of genomic sequence, and fragments of the MUC5B genomic sequences have been published in various literatures (Specification, paragraph 0007-0009). However, the full-length genomic sequence of the MUC5B gene and various fragments and allelic variants of the MUC5B gene are yet to be determined to this today. Apparently, at the time the present application was filed, applicants were not in possession of the genus of the nucleic acids comprising SEQ ID Nos: 31 and/or 32, which are encompassed by the instant claim.

The claimed nucleic acid encompasses a considerable number of genomic sequences of the MUC5B gene varying in length, sequence components, and functions. The specification fails to provide an adequate description to teach the structure and function of these molecules, and accordingly does not provide a reasonable guide for those seeking to practice the invention. An adequate written description of a nucleic acid requires more than a mere statement that it is part of the invention and reference to

a potential method for isolating it; what is required is a description of the structure of the nucleic acid itself. Also, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. Since the unknown genomic sequences of MUC5B could not be determined by the identities of SEQ ID Nos: 31 and 32, claiming all nucleic acids that containing SEQ ID Nos: 31 and 32 without defining their sequences is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)).

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

In view of these considerations, a skilled artisan would not have viewed the teachings of the specification as sufficient to show that the applicant was in possession of the claimed invention commensurate to its scope.

Please not that claims 2-5 are included in this and the following rejection because they contain the nucleic acid of claim 1 which has not been adequately described.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether the disclosure satisfies the enablement requirements and whether undue experimentation would be required to make and use the claimed invention (see *In re Wands*, 858 F. 2d 731, 737, 8 USPQ 2d 1400, 1404, 1988). These factors include but are not limited to the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability of the art, the breadth of the claims, and amount of direction provided.

These claims encompass fragments, allelic variants and full-length genomic sequences of the MUC5B gene, however, as indicated *supra* in the written description section, the specification fails to provide an adequate description for aforementioned sequences. Since the disclosure fails to describe these nucleic acid molecules, one cannot extrapolate the teachings of the specification to the scope of the claims because the skilled artisan cannot envision the detailed structure of nucleic acids encompassed by these claims and would not know how to use the invention without first carrying out

undue experimentation to determine the sequences of the molecules embraced by the claims.

Therefore, in view of the limited guidance, the lack of predictability of the art, and the breadth of the claims, one skill in the art could not practice the invention without undue experimentation as it is broadly claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipate by *Chen et al* (Gene Bank Accession No. AF107890, Released 2000 Nov. 22, IDS/14).

Claim 1 is drawn to an isolated nucleic acid molecule comprising a nucleotide sequence selected from the group consisting of SEQ ID No: 31 and 32.

Chen et al disclose an isolated nucleic acid molecule AF107890 (partial genomic sequence of MUC5B) comprising both SEQ ID No: 31 and 32. Therefore, *Chen et al* anticipate the instant claim.

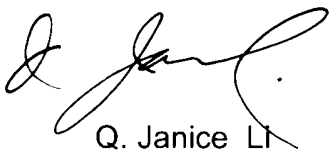
No claim is allowed. Claims 2-5 appear to be free of cited prior art of record, however, they are subject to other rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).



Q. Janice Li
Examiner
Art Unit 1632

QJL
May 2, 2003